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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,706	09/11/2003	Simon L. McGurk	029318-0968	4753
31049 7590 11/19/2008 Elan Drug Delivery, Inc. c/o Foley & Lardner 3000 K Street, N.W. Suite 500 Washington, DC 20007-5109				
EXAMINER				
SILVERMAN, ERIC E				
ART UNIT		PAPER NUMBER		
1618				
MAIL DATE		DELIVERY MODE		
11/19/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/659,706

Applicant(s)

MCGURK ET AL.

Examiner

ERIC E. SILVERMAN

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-47 is/are pending in the application.
- 4a) Of the above claim(s) 9-11, 23, 29 and 44-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7, 8, 12-22, 24-28, 30-43 and 47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/22/2008 has been entered.

Claims 1-5 and 7-47 are pending, claims 9-11, 23, 29, and 44-46 are withdrawn, and claims 1-5, 7, 8, 12-22, 24-28, and 30-43 and 47 are treated on the merits in this action.

Response to Arguments

Applicant's arguments with respect to claims 1-5, 7, 8, 12-22, 24-28, and 30-43 and 47 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim requires that at least 70%, 90% or 95% of the active agent particles have a particle size less than the effective average particle size. It is not clear how the

vast majority of particles could have sizes below the average size; in a manufacturing process, particles of a particular average size would be expected to have a Gaussian-type distribution centered at the average size.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 7, 8, 12-22, 26-28, 30-43 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,882,157 to Yang in view of US 4,837,255 to Dechow.

Yang teaches confectionary delivery systems from anti-cholesterol medicaments. The delivery system includes active drug particles coated with one or more stabilizing materials, such as PEG of instant claim 28. The particles are homogeneously dispersed in gelatin matrices, the matrices comprising gelatin, sweeteners, and other pharmaceutically acceptable materials. The composition has from 1% - 30% water by weight, which substantially overlaps with instantly claimed amount of water. The examples show compositions having the various components within the amounts required by instant claims. The product is formed in rectangular molds, which is a geometric shape. A confectionary is formulated for oral administration. With regard to claim 16, the claim encompasses all types of release profiles, therefore Yang must read on it. With regard to claim 18, the alternatively recited types of particles encompass all particles, and is therefore read on by Yang. Yang 's preferred drug, cholestyramine, is

poorly soluble within the meaning of that term in claims 19-21. Yang's teaching of at least one surface stabilizer is suggestive of two, and the oxyethylene taught as a coating reads on nonionic stabilizers of claim 27.

Yang does not teach the requisite particle size, nor the type of gelatin.

Dechow teaches gelatin formulations for delivery of a resin for reducing cholesterol. The resin has an average particle size from 20 – 100 microns, which overlaps with instant "less than about 2000 nm". Dechow also teaches gelatin USP type A, which is understood to read on the gelatin instantly claimed.

Claims 30-43 recite properties of the composition, which are inseparable from the composition itself. Claim 47 recites a product by process claim, wherein the Yang and Dechow references teach the same product, although the process may not be the same.

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to use particles of the sizes taught, and gelatin of the type taught, in Dechow. Obviousness stems from the notion that Yang merely requires "fine" (less than 70 mesh) particles, and does not specify the type of gelatin, whereas Dechow fills in the optimal types of gelatin and particle sizes for systems of the same type.

Claims 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yang in view of Dechow, as applied to claims 1-5, 7, 8, 12-22, 26-28, 30-43 and 47 above and in further view of US 4,003,999 to Lybrand et al.

Lybrand teaches that acetylsalicylate (aspirin) is a useful anti-inflammatory; aspirin is also a known analgesic.

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to use acetylsalicylate as an active agent in Yang and Dechow. The artisan practicing that invention, and wanting to achieve the relief of inflammation and pain that often accompanies other ailments, would be find it obvious to add acetylsalicylate according to Lybrand.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC E. SILVERMAN whose telephone number is (571)272-5549. The examiner can normally be reached on Monday to Thursday 7:00 am to 5:00 pm and Friday 7:00 am to noon.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571 272 0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric E Silverman/
Examiner, Art Unit 1618